EXHIBIT 2

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

WARREN L. SMITH and KAREN F. SMITH,	*	
	*	
Plaintiffs,	*	
	*	
V.	*	Civil Action No.
	*	
AMERIDOSE LLC, MEDICAL SALES MANAGEMENT INC., GDC PROPERTIES MANAGEMENT, LLC, BARRY J. CADDEN, LISA CONIGLIARO CADDEN, GLENN A. CHIN, GREGORY CONIGLIARO, and ARL BIO PHARMA, INC. D/B/A/ ANALYTICAL RESEARCH LABORATORIES,	*	
	*	
Defendants.	*	

COMPLAINT AND JURY DEMAND

The Plaintiffs, Warren Smith and Karen Smith, through counsel, bring this Complaint and Jury Demand, against the Defendants, Ameridose LLC, Medical Sales Management Inc., GDC Properties Management, LLC, Barry J. Cadden, Lisa Conigliaro Cadden, Glenn A. Chin, Gregory Conigliaro, and ARL BIO PHARMA, INC. d/b/a Analytical Research Laboratories, and for their causes of action, allege as follows:

INTRODUCTION

1. A widespread outbreak of fungal meningitis this year has affected people in at least 23 states and caused at least 48 deaths at the time of this Complaint. At a minimum 707 people have been diagnosed with meningitis and over 17,000 people continue living in fear of contracting the disease and the prospect of painful diagnostic testing and

long difficult treatment. This preventable outbreak originated from a medication compounded and distributed by Defendants. The Food and Drug Administration (FDA) and the Centers for Disease Control (CDC) have identified bacteria present in several separate lots of the Defendants-supplied preservative-free injectable steroids, specifically, methylprednisolone acetate ("MPA"); ophthalmic injectable drugs; and cardioplegia solutions.

2. The FDA and CDC have implicated Defendants' facilities as the cause of the injuries and death. Defendants' facilities were shamefully unsterile, replete with fungus that contaminated the vials holding the medications. Defendants' blatant disregard for even the most basic sterility obligations, their wanton disregard for the limited scope of their licenses, their conscious disregard for safety standards, their deplorable facility conditions where mold and bacteria festered, and blatant contempt for prior complaints, adverse events, and inspection findings, along with other Defendants' woefully insufficient testing, inadequate warning, overt misrepresentations, and knowing distribution of products compounded amidst such wrongful conduct, all led to a national epidemic of fungal meningitis.

3. Multiple vials of steroids, along with scores of other medications developed at the Defendants' facilities have been recalled, but the recall was too late for Plaintiffs, Warren Smith and Karen Smith, and for many others who have suffered serious, and at times catastrophic, injuries.

PARTIES

4. Plaintiff, Warren L. Smith, is a United States citizen and resides at 7301 Brookeville Road, Plymouth, Michigan 48170.

5. Plaintiff, Karen F. Smith, is a United States citizen and resides at 7301 Brookeville Road, Plymouth, Michigan 48170.

6. Plaintiffs, Warren Smith and Karen Smith, are and, at all times relevant, were husband and wife.

7. Defendant, Ameridose LLC ("Ameridose") is a Massachusetts limited liability company with a principal place of business at 203 Flanders Road, Westborough, Massachusetts 01581. Ameridose is owned by Carla Congiliaro, Barry Cadden, Lisa Cadden, and Gregory Conigliaro. The managers of Ameridose are Gregory Congiliaro and Barry Cadden. Ameridose's registered agent is Gregory Congiliaro.

8. Defendant, Medical Sales Management Inc. ("MSM"), is a Massachusetts corporation with a principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Defendant, Douglas Conigliaro, is the President of MSM. Defendant, Barry Cadden, is the Treasurer of MSM. Defendant, Gregory Conigliaro is the Secretary of MSM. MSM's registered agent is Gregory Conigliaro.

9. Defendant, GDC Properties Management, LLC ("GDC"), is a Massachusetts limited liability company with a principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

10. Defendant, Barry J. Cadden ("Barry Cadden") is an individual person

residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. Barry Cadden is the President of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record, as that term is defined by 247 CMR 2.00. Barry Cadden was a founder and Manager of Ameridose and was involved in Ameridose's day to day operations. Barry Cadden was the Treasurer and Director of MSM.

11. Defendant, Lisa Conigliaro Cadden ("Lisa Cadden") is an individual person residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.

12. Defendant, Glenn A. Chin ("Glenn Chin") is an individual person residing at 173 Mechanic Street, Canton, Massachusetts 02021. At least until October 2012, Glenn Chin was a pharmacist at NECC.

13. Defendant, Gregory Conigliaro ("Gregory Conigliaro"), is an individual person residing at 1 Mountain View Drive, Framingham, Massachusetts 01701. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is founder and Manager of Ameridose and involved in Ameridose's day to day operations. Gregory Conigliaro is Secretary and Director of MSM.

14. Defendant ARL BIO Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. The Chief Executive Officer of ARL is Thomas C. Kupiec.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

16. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (c).

17. At all times relevant hereto, several of the Defendants were engaged in the business of developing, manufacturing, marketing, distributing, promoting and/or selling either directly, or indirectly through third parties or other related entities, steroids and other drugs in the Commonwealth of Massachusetts and in interstate commerce, from which they derived significant and regular income.

18. Defendants also have their principal places of business and/or residences in Massachusetts. Defendants are all citizens of Massachusetts.

STATEMENT OF THE FACTS

F. RELEVANT BACKGROUND

19. NECC is a compounding pharmacy that compounds, manufacturers, distributes and/or sells drugs to purchasers throughout the United States, including

Michigan.

20. NECC is a privately-held company that is owned and controlled by Barry Cadden, Gregory Conigliaro, Carla Conigliaro and Lisa Cadden.

21. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden also was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications, including methylprednisolone acetate, at NECC.

22. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

23. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).

24. At least until October 2012, Gregory Conigliaro was involved in managing the day-to-day operations of NECC, MSM, Ameridose and GDC.

25. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications, including methylprednisolone acetate, at NECC.

26. At least until October 2012, Glenn Chin was a licensed pharmacist who,

upon information and belief, compounded medications, including methylprednisolone acetate, at NECC.

27. Ameridose, according to an application signed by Gregory Conigliaro and notarized by Michelle Rivers, and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership – currently Ameridose, Alaunus and NECC, as well as other Properly Licensed Facilities in the future."

28. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC. In 2005, NECC hired and paid Sophia Pasedis, a member of the Massachusetts Board of Registration in Pharmacy, to consult with NECC on the formation and establishment of Ameridose.

29. On April 11, 2011, Ameridose employee, Michelle Rivers, requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

30. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com. Upon information and belief, there were many other occasions where employees of Ameridose and/or MSM would perform services for NECC.

31. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for

employees of both companies. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members. MSM printed materials for and marketed both NECC's and Ameridose's products, including methylprednisolone acetate. One former employee of MSM has stated: "I didn't think there was any difference [between Ameridose and NECC]."

32. Through September 2012, both NECC and Ameridose used MSM for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

33. According to its Internet website, "ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry."

34. According to its Internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."

35. ARL also states on its Internet website that it follows "USP monographs/general chapters[,]" and that it has a formal Quality Assurance Program in compliance with "USP monographs/general chapters[.]"

36. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: "Your customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. ***You should expect nothing less from the testing***

laboratory you entrust." (emphasis in original).

37. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL's "**[t]esting methods and technologies [are] unparalleled in the market today**[.]" (emphasis in original).

38. With respect to its sterility tests, ARL, on its Internet website, states: "We examine each sterility test for growth at days 2, 3, 7 and 14 and log the result. If a test shows no evidence of microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation."

39. GDC owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

40. From 1998 until at least October 2012, GDC leased a portion of the premises at 697 Waverly Street to NECC.

41. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations."

42. GDC maintained a high degree of control over the premises leased by NECC.

43. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden

and Glenn Chin compounded, tested, marketed and/or distributed methylprednisolone acetate. Methylprednisolone acetate is a steroid that is used, *inter alia*, to treat neck and back pain. Methylprednisolone acetate is administered via epidural injection to patients suffering from neck and back pain.

44. GDC knew that NECC was compounding preservative-free methylprednisolone acetate at 697 Waverly Street, and GDC knew that this medication was injected into humans and was required to be sterile.

45. Until October 2012, NECC compounded methylprednisolone acetate at its facility in Framingham, Massachusetts, and NECC sold tens of thousands of vials of methylprednisolone acetate to healthcare providers across the country.

46. On September 21, 2012, the Centers for Disease Control and Prevention (the "CDC") was notified by the Tennessee Department of Health of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.

47. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

48. According to the CDC, symptoms for meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis.

49. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms.

50. In late September 2012, NECC recalled the following lots of methylprednisolone acetate (PF) 80mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

51. NECC identified Michigan Pain Specialists in Brighton, Michigan as one of the healthcare facilities that received vials of methylprednisolone acetate that were part of the September 2012 recall.

52. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."

53. In NECC's October 6, 2012, press release, NECC advised that it was "notifying its customers of this recall by fax[,]" and that "[c]linics, hospitals and healthcare providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax

notice."

54. In NECC's October 6, 2012, press release, NECC explained that "[p]roducts from NECC can be identified by markings that indicate New England Compounding Center by name or by its acronym (NECC), and/or the company logo[,]" which logo appears as:

55. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.

56. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin voluntarily ceased their practice as pharmacists until at least December 31, 2012. Lisa Cadden also has voluntarily ceased her practice as a pharmacist until at least December 31, 2012. Upon information and belief, none of them have practiced as a pharmacists since voluntarily ceasing their practice.

57. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

58. Over the last ten years, ARL has conducted sterility testing on samples of

methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

59. From May through August 2012, NECC sent several samples of its methylprednisolone acetate to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

60. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

61. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

62. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

63. On or about August 10, 2012, NECC caused one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several

thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

64. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were conducted in compliance with USP 71.

65. During the summer of 2012, MSM sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

66. ARL was well aware of the risk posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

67. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

68. In 2005, ARL's Chief Executive Officer, Thomas Kupiec, wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

69. In 2007, Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

70. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding[,]" which stated that there had been "more than 200 adverse events involving 71 compounded products since 1990. Some of these instances had

devastating repercussions."

71. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to be tested in relation to the number of articles in the batch" and a "14-day quarantine of the drug to await final test results[,]" Kupiec wrote in a 2007 published article that there should be "separate standards for compounding pharmacies and manufacturers."

72. While the requirements of USP 71 were not relaxed for compounding pharmacies after Kupiec's 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

73. Other testing laboratories that perform sterility testing on drugs compounded by compounding pharmacies request double the number of samples required by USP 71.

74. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of methylprednisolone acetate. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Glenn Chin, Ameridose, MSM and GDC knew or should have known of these findings. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Glenn Chin, Ameridose, MSM and GDC failed to investigate those isolates and made no effort to identify those isolates. NECC, Barry

Cadden, Gregory Conigliaro, Lisa Cadden, Glenn Chin, Ameridose, MSM and GDC failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Glenn Chin, Ameridose, MSM and GDC failed to take any corrective actions with regards to the isolates that were found. Despite these findings, NECC continued to compound methylprednisolone acetate, and MSM continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

B. GENERAL ALLEGATIONS DEFENDANTS KNOWINGLY OPERATED BEYOND THE SCOPE OF THEIR LICENSES.

75. The Massachusetts Board of Registration in Pharmacy licensed NECC as a compounding pharmacy. NECC is licensed to provide medication compounding services, which involves modifying commercially available products to meet individual patient needs pursuant to a prescription from a licensed healthcare provider. Compounding pharmacies and their pharmacists may perform compounding services only upon receipt of a patient-specific prescription. They custom mix drugs according to industry standards such as guidelines from the U.S. Pharmacopeial Convention, a nonprofit organization that provide guidance regarding how to produce small quantities of sterilized products for specific patients. Those standards do not translate well when applied to greater scale manufacturing of large batches.

76. Since at least 1999, large batches of compounded drugs by Defendant pharmacists from NECC's facility were developed for wide-scale distribution and general use rather than requiring a prescription for an individual patient. Manufacturing and

distributing sterile products in bulk exceeds the permissible scope of NECC's and the pharmacist Defendants' state pharmacy licenses. Operating in this manner exposed the Defendants to additional levels of requirements and industry standards. Instead, Defendants knowingly ignored the patient specific prescription requirements and even suggested ways to skirt the law to various customers including a Wisconsin pharmacy in 2004.

C. DEFENDANTS IGNORED SAFETY STANDARDS BY PRODUCING DRUGS IN A DEPLORABLE NON-COMPLIANT FACILITY.

77. The Massachusetts Department of Public Health and FDA investigators identified serious deficiencies and significant violations that clearly placed the public's health and safety at risk. Each Agency has released reports on Defendants' longstanding widespread disregard for safety. Some examples follow. The conditions were so bad, FDA issued a Form 483 identifying eight pages of observed conditions or practices that may indicate violations of the Federal Food, Drug, and Cosmetic Act, or related regulations.[1] The findings reveal repulsive conditions where bacteria and mold fester throughout the facility and equipment.

78. In early October 2012, FDA investigators located fungal contamination in a sealed vial of the steroid at NECC's facilities on GDC's property. FDA's findings prompted NECC to recall 17,676 single-dose vials of the steroid.

79. Even though NECC recalled the steroid in early October, thousands of people at outpatient clinics and similar facilities in 23 states were injected with the steroid between July and September 2012.

[1] Plaintiff is not asserting a private cause of action based on any FDA regulations.

80. The Massachusetts Department of Public Health (DPH) investigators, in collaboration with investigators from the U.S. Food and Drug Administration (FDA), investigated NECC and release preliminary findings on October 23, 2012.

81. As an initial matter, the DPH: "Upon beginning the joint on-site investigation of NECC early in this outbreak, DPH and FDA investigators identified serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk."

82. In its preliminary findings the DPH found: "During the facility inspections, investigators documented serious health and safety deficiencies related to the practice of pharmacy. All pertain to violations of 247 CMR 9.01(3) or 247 CMR 6.01(5)(a):

1. NECC distributed large batches of compounded sterile products directly to facilities apparently for general use rather than requiring a prescription for an individual patient.

    a. Records show that NECC had lists of potential patient names but did not have patient-specific prescriptions from an authorized practitioner when compounding and dispensing medication, as required by state law.

    b. Manufacturing and distributing sterile products in bulk was not allowed under the terms of its state pharmacy license. If NECC was appropriately licensed as a manufacturer with the FDA the company would have been subject to additional levels of scrutiny.

    c. NECC did not conduct patient-specific medication history and drug utilization reviews as required by regulations.

2. NECC distributed two of the recalled lots of methylprednisolone acetate (PF) 80 MG/ML prior to receiving results of sterility testing:

    a. Lot *06292012@26* was prepared on June 29, 2012. Final sterility testing was completed on July 17, 2012. Two shipments of product were made prior to the final sterility tests results being received.

b. Lot *08102012@51* was prepared on August 10, 2012. Final sterility testing was completed on August 28, 2012. Eleven shipments of product were made prior to the final sterility tests results being received.

3. Final sterilization of product did not follow proper standards for autoclaving (sterilization through high pressure steam) pursuant to United States Pharmacopeia Standard 797 (USP 797) and NECC's own Standard Operating Procedures: Examination of NECC records indicated a systemic failure to keep products in the autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

4. NECC did not conduct proper validation of autoclaves pursuant to USP 797: NECC failed to test their autoclaves to ensure proper function.

5. Visible black particulate matter was seen in several recalled sealed vials of methylprednisolone acetate from Lot *08102012@51*.

6. Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation, within the sterile compounding area were not thoroughly cleaned pursuant to USP 797. Residual powder was visually observed within the hood during inspection. This contamination may subsequently lead to contamination of compounded medications.

7. Condition of "Tacky" mats, which are used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry, violated the USP 797. Mats were visibly soiled with assorted debris.

8. A leaking boiler adjacent to the requisite clean room created an environment susceptible to contaminant growth: A pool of water was visually observed around the boiler and adjacent walls, creating an unsanitary condition; the culture results of this potential contaminant are still pending."

83. Surface samples from NECC's "clean" rooms revealed bacteria and mold, as did various equipment and parts of the facility. Air sampling showed "1 big mold" as far back as May 29, 2012. Air sampling throughout the facility revealed mold and bacteria. Dozens of results exceeded the "action level." "There was no investigation conducted by the

firm when levels exceeded their action limits and there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacteria and mold) from the facility."

84. Environmental monitoring procedures require sampling. Records showed mold and bacteria. "These results were not investigated and there was no identification of the isolates. There were no product impact assessments performed for any sterile products that were made in the hoods or gloveboxes on the days the samples were taken. In addition, the firm has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products."

85. FDA observed greenish yellow discoloration lining the interior surface of the viewing lens within the "Inside" autoclave used for steam sterilization of various components and equipment (e.g. vials of multiple sizes, stoppers, and spin bars) used in the formulation of sterile drug products. FDA further observed condensation along the interior surfaces of the "Outside" autoclave to collect in a pool at the base of the chamber.

86. The investigators also observed problems with NECC's ability to maintain its clean room, which is the enclosed space that is designed and maintained to have a controlled environment with low levels of airborne particles and surface contamination. Production of sterile drug products in a properly functioning and maintained clean room reduces the risk of microbial contamination.

87. A used mattress processing facility abuts and operates under the same roof as NECC's facility. As FDA noted in its inspection, "The firm is abutted to the rear and along the left parking area by a recycling facility that handles such materials as mattresses

and plastics. On 10/02/2012, the area was observed to include large equipment (e.g. excavators and freight trucks) producing airborne particulates (e.g. dust). Rooftop units serving the firm's HVAC system were estimated to be located approximately 100 feet from the recycling facility."

88. NECC personnel have handled drug vials without proper equipment and wearing proper safety clothing.

89. FDA observed what appeared to be white filamentous substances covering the HVAC return located behind the autoclave located in the firm's Middle Room (ISO 7). This autoclave is used for the steam sterilization of formulated bulk drug suspensions. FDA further observed greenish residue covering the surface of the ceiling exposed to the filter above, within Weigh Station 3 Hood located in the firm's ISO 6 Clean Room. The firm uses Weigh Station Hoods to weigh active ingredients and other raw materials utilized in the formulation of sterile drug preparations.

90. In sum, FDA observed bacteria and mold growing all over the firm's "sterile" facility, one it repeatedly represented to customers was "state-of-the-art" and used to produce "highest quality compounded medications."

91. Such violations constitute gross negligence, if not recklessness. As a result, NECC's facility on GDC's property has been closed and the pharmacists Defendants' licenses recommended to be revoked if not voluntarily surrendered. Unfortunately it's too late for the hundreds that have suffered, including the Plaintiffs, and many that have died.

92. MSM marketed and Ameridose distributed the products compounded in such deplorable conditions

D. DEFENDANTS DISREGARDED PRIOR COMPLAINTS AND INSPECTIONS BY CONTINUING IMPERMISSIBLE CONDUCT AND IGNORING SAFETY RISKS.

93. Defendants effectively ignored dozens of complaints from as early as April 1999. In 2002, two patients suffered an adverse effect after taking an NECC compounded steroid used to treat joint pain and arthritis. One victim subsequently died. FDA notified the state pharmacy board in October 2002 about an incident involving a drug the company had produced, methylprednisolone acetate, which is the same steroid linked to the outbreak.

94. In 2004, an inspector report revealed that a toxin had been found in an NECC drug and that the company could not produce various records about the drug, including test results on its sterility. NECC and other Defendants failed to meet accepted standards that year for making the same steroid.

95. A 2006 letter to NECC from Pharmacy Support Inc, an outside evaluation firm observed that the company continued to have significant gaps in its sterile compounding operation. That same year FDA issued warning letters to NECC. NECC and other Defendants received other warnings as well.

96. NECC and other Defendants solicited out-of-state prescriptions for office use and used unapproved forms. NECC and other Defendants were aware of complaints regarding this practice and its improper promotional material and methods, but turned a blind eye to it all.

E. DEFENDANTS WANTONLY EXPOSED PLAINTIFFS TO THIS TOXIN.

97. On August 8, 2012, Defendants caused 400 vials of methylprednisolone acetate contaminated with fungi and other contaminants to be shipped to Michigan Pain Specialists in Brighton, Michigan. Upon information and belief, Ameridose distributed these vials to the Michigan Pain Clinic on behalf of NECC.

98. On or about August 13, 2012, Plaintiff, Warren L. Smith, was a patient at Michigan Pain Specialists in Brighton, Michigan, where he was administered an interlaminar lumbar epidural steroid injection of 80 mg of methylpredisolone acetate.

99. On or about September 10, 2012, Mr. Smith received a second epidural steroid injection of 80 mg of methylpredisolone acetate at Michigan Pain Specialists in Brighton.

100. Unknown to Mr. Smith and the administering physician, the methylpredisolone acetate that was injected into Mr. Smith's back in August and September 2012 was contaminated with fungal meningitis. The lot that contained the vial of MPA administered to Mr. Smith was to be recalled in later that month.

101. Since his second injection on September 10, 2012, Mr. Smith has been diagnosed with meningitis and has suffered photosensitivity, headaches, back pain, vomiting, difficulty walking, and the development of an abscess, requiring painful diagnostic procedures and surgical intervention, a painful course of medication, hospital stays exceeding two months, and ongoing treatment and monitoring.

102. On October 19, 2012, Plaintiff, Warren Smith, was admitted to St. Joseph Mercy Hospital in Ann Arbor, with symptoms of severe headache, severe back and leg pain

and difficulty walking. At that time, he was diagnosed with and treated for fungal meningitis, secondary to contaminated steroid injections. Mr. Smith remained hospitalized for 10 days until he was discharged on October 29, 2012.

103. Initially, after the October 29, 2012 discharge, Mr. Smith progressed as expected; however, within days, his symptoms returned, and on November 7, 2012, Mr. Smith was again admitted to St. Joseph Mercy Hospital in Ann Arbor. At that time, an MRI of Mr. Smith's spine revealed dural thickening and enhancement compatible with meningitis. Mr. Smith was advised that he would need surgery to remove an abscess.

104. On November 8, 2012, Mr. Smith underwent a lumbar laminectomy, epidural phlegmon and exploration at St. Joseph Mercy Hospital. Surgical pathology confirmed fungal epidural abscess.

105. Mr. Smith remained hospitalized for two months. He was discharged on January 4, 2013.

106. Mr. Smith has been completely debilitated as a result. Mr. Smith can now barely walk. He has been rendered a shell of the man he used to be. He has suffered unspeakable personal injuries, physical and emotional distress, and has incurred medical and other expenses as a direct result of being injected with Defendants' contaminated and defective methylpredisolone acetate ("MPA"). As a further result of the injuries Mr. Smith has sustained, Mr. Smith has been unable to return to work and oversee his hardware business since his hospitalization in October.

107. In addition, Plaintiff, Karen F. Smith, has suffered loss of consortium. The marital relationship between Mr. and Mrs. Smith has been damaged as a direct result of

Mr. Smith being injected with contaminated methylpredisolone acetate. Mrs. Smith has suffered mentally, emotionally and physically watching her husband suffer and feeling frustrated at being unable to help him feel better. In addition, she has suffered financially because she has had to take a leave of absence from work to care for and support her husband.

108. As of February 22, 2013, there have been 707 cases of fungal meningitis and infections associated with contaminated methylprednisolone acetate compounded by Defendants, with 48 deaths reported nationwide. Michigan has the highest number of such cases, with two 223 cases reported and ten deaths.

109. On December 20, 2012, CDC issued a Health Alert Network notice providing updated guidance and information about the ongoing multistate outbreak of fungal infections attributed to contaminated methylprednisolone acetate. In summary, the notice disclosed that many patients who received injections of the contaminated methylprednisolone acetate have developed localized spinal or paraspinal infection, including epidural abscess, phlegmon, arachnoiditis, discitis, and vertebral osteomyelitis.

110. Defendants and their agents at all times were expected to provide proper maintenance, oversight, security and control of its laboratory, manufacturing facility, distribution facility and other units. Defendants were at all times under a duty to maintain procedures that protect patients and end consumers of the products Defendants marketed, sold, manufactured, tested and/or distributed from infections and medical conditions through contaminated steroid medications or other medications.

111. Upon information and belief, the contaminated steroid medication injected

into Plaintiff's body was marketed, sold, compounded, manufactured, tested and/or distributed by Defendants and Plaintiffs were injured by their wrongful conduct.

112. The products ingredients were obtained from other entities whose identities are not yet known.

COUNT I

NEGLIGENCE

(Against All Defendants)

113. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

114. As the designer, tester, compounder, manufacturer, seller, marketer and / or distributor of consumer products, Defendants owed a duty to Plaintiffs to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to the plaintiff Mr. Smith.

115. Specifically, but without limitation:

a. Barry Cadden, Gregory Conigliaro, Lisa Cadden, Glenn Chin, Ameridose and MSM owed Plaintiffs a duty to provide methylprednisolone acetate that was safe and free of contamination.

b. ARL owed Plaintiffs a duty to properly conduct tests to insure that the methylprednisolone acetate was safe and free of contamination.

116. Defendants breached those duties, and were otherwise negligent in their design, manufacture, compound, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to the Plaintiff. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, manufacturer, compounder, tester, seller, marketer and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through its supervisors, staff and agents engaged in compounding, creating, designing, manufacturing, storing, testing, selling, marketing and distributing the medicine in a negligent manner.

117. Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, manufacture, test, distribute, produce and market safe steroid medication; by failing to properly maintain its facilities where it manufactured its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its manufacturing and distribution facilities and other units; and by allowing, distributing and marketing contaminated and unsafe medications compounded to reach the stream of commerce for use by Plaintiff.

118. Barry Cadden, Gregory Conigliaro, Lisa Cadden, Glenn Chin, Ameridose, MSM and ARL breached the duties owed to Plaintiffs by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.

119. The negligence of Barry Cadden, Gregory Conigliaro, Lisa Cadden, Glenn

Chin, Ameridose, MSM, ARL and GDC was a proximate cause of Plaintiffs' injuries.

120. Plaintiff was actually exposed to fungal meningitis through NECC's contaminated steroid vial that was injected into him in August and September, 2012.

121. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Mr. Smith has suffered injuries and damages including but not limited to pain and suffering, emotional distress, anxiety, emotional damage and has incurred medical and other expenses. Such damages render him no longer able to engage in his daily activities and enjoyment of life.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, in an amount that will justly compensate them for their damages and future losses, together with interest, costs and his attorneys' fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT II

NEGLIGENCE PER SE

(Against All Defendants)

122. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

123. Barry Cadden, Gregory Conigliaro and GDC owed Plaintiffs a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

124. Barry Cadden, Gregory Conigliaro and GDC breached the duties owed to Plaintiffs by failing to use reasonable care in maintaining the premises of the pharmacy "in

a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

125. Defendants also violated Massachusetts' laws and its pharmacy licensing obligations.

126. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Mr. Smith has suffered injuries and damages as described with particularity, above.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, in an amount that will justly compensate them for their damages and future losses, together with interest, costs and his attorneys' fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT III

NEGLIGENT SUPERVISION

(Against Defendants Barry Cadden, Gregory Conigliaro, GDC, MSM and ARL)

127. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

128. Defendants had an obligation and duty to exercise due care, and comply with the then existing standard of care, to investigate and hire professional and competent employees to manufacture, create, test, package, market and distribute the compounded medications and the maintain the facility and its premises, and to make sure the compounded drugs do not create any harm or risk to the Plaintiff receiving the medication.

129. In breach of those duties, Defendants failed to exercise due care and failed

to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

a. The Defendants failed to monitor and test the manufacture of the steroid medication and were otherwise negligent in supervision of their employees.

b. Defendants also failed to monitor and supervise the testing of the compounded medications.

c. The Defendants were negligent in hiring, training, and supervising their employees.

130. The Defendants knew, or should have known, that the employee or agent did not follow proper procedures and knew or should have known of the risks created by failing to do so.

131. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including the Plaintiff, Warren Smith.

132. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Mr. Smith has suffered injuries and damages as described with particularity, above.

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, in the amount that will justly compensate them for their damages and future losses, together with interest, costs and his attorneys' fees incurred in this action.

COUNT IV

NEGLIGENT MISREPRESENTATION

(Against MSM and Ameridose)

133. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

134. The Plaintiff, through his health care providers, relied on material statements concerning the safe use of the steroid medication marketed and distributed by MSM and Ameridose which was within Defendants' own knowledge.

135. Defendants MSM and Ameridose provided express and/or implied representations that the steroid medication was safe to use by Plaintiff.

136. This representation was made for the purpose of inducing the Plaintiff, through his physician, to purchase the steroid medication to alleviate his pain.

137. This representation was material to the transaction.

138. This representation was not true.

139. The Plaintiffs justifiably relied on the misrepresentation.

140. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Mr. Smith has suffered injuries and damages as described with particularity, above.

WHEREFORE, the Plaintiffs demand judgment against Defendants MSM and Ameridose, jointly and severally, on Count IV of this Complaint, in the amount that will justly compensate them for their damages and future losses, together with interest, costs and their attorney's fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT V

BREACH OF IMPLIED WARRANTY

(Against Barry Cadden, Gregory Conigliaro, Lisa Cadden, Glenn Chin, Ameridose, MSM, and ARL)

141. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

142. The contamination of NECC and other Defendants' methylprednisolone acetate was present at the time the drug left the facilities' possession and control.

143. The contaminated methylprednisolone acetate was not altered in any way after it was sold by NECC and other Defendants, and the drug was used as intended.

144. Barry Cadden, Gregory Conigliaro, Lisa Cadden, Glenn Chin, Ameridose, MSM and ARL breached the implied warranty of merchantability by failing to use reasonable care in compounding, testing, marketing and/or distributing methylprednisolone acetate.

145. The breaches by Barry Cadden, Gregory Conigliaro, Lisa Cadden, Glenn Chin, Ameridose, MSM and ARL of the implied warranties of merchantability were a proximate cause of Plaintiff's injuries.

146. As a direct and proximate result of the acts and omissions of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Mr. Smith has suffered injuries and damages as described with particularity, above.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, on Count V of this Complaint, in the amount that will justly compensate them for

their damages and future losses, together with interest, costs and their attorney's fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT VI

PUBLIC NUISANCE

(Against Barry Cadden, Gregory Conigliaro and GDC)

147. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

148. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

149. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

150. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

151. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.

152. Barry Cadden, Gregory Conigliaro and GDC unreasonably and

significantly interfered with the public health and the public safety.

153. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

154. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC was a proximate cause of Plaintiffs' injuries.

155. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC has caused Mr. Smith special injury in that Mr. Smith has sustained injuries to his personal health.

156. As a direct and proximate result of the acts and omissions of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Mr. Smith has suffered injuries and damages as described with particularity, above.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, on Count VI of this Complaint, in the amount that will justly compensate them for their damages and future losses, together with interest, costs and their attorney's fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT VII

LOSS OF CONSORTIUM

157. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

158. Plaintiffs, at all times relevant hereto, were and continue to be husband and wife.

159. Plaintiff, Karen F. Smith, as a result of the injuries sustained by Plaintiff, Warren L. Smith, described above, has suffered loss of consortium. She has suffered, and will continue to suffer in the future, mental anguish, the loss of support, love, companionship, affection, society, sexual relations, solace and other damages.

160. In addition, the marital association between Mr. and Mrs. Smith has been damaged as a direct result of Mr. Smith's use of the Defendants' defective and contaminated steroid injection.

WHEREFORE, the Plaintiff, Karen Smith, demand judgment against Defendants, jointly and severally, on Count VII of this Complaint, in the amount that will justly compensate them for their damages and future losses, together with interest, costs and their attorney's fees incurred in this action, all within the jurisdictional limits of this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, as follows:

1. Economic and non-economic damages and damages for pain and suffering and loss of basic and pleasurable activities in an amount in excess of $75,000 as provided by law and to be supported by the evidence at trial;

2. For compensatory and other damages according to proof;

3. For punitive damages as allowed by law;

4. For an award of attorneys' fees and costs;

5. For prejudgment interest and the costs of suit; and

6. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a jury trial on all claims so triable in this action.

Respectfully submitted,

PLAINTIFFS WARREN and KAREN SMITH,

By Their Counsel,

/s/ Kimberly Dougherty
Kimberly Dougherty, Esquire
BBO# 658014
Janet, Jenner & Suggs, LLC
75 Arlington Street
Suite 500
Boston, MA 02116
Phone: (617) 933-1265
Fax: 410-653-6903
Email: kdougherty@MyAdvocates.com

Robert K. Jenner (*pro hac vice* motion to be filed)
Elisha Hawk (*pro hac vice* motion to be filed)
Janet, Jenner & Suggs, LLC
1777 Reisterstown Road, Suite 165
Baltimore, MD 21208
Phone: (410) 653-3200
Fax: (410) 653-6900
Email: rjenner@MyAdvocates.com
Email: ehawk@MyAdvocates.com

JS 44 (Rev. 09/11)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
WARREN L. SMITH and KAREN F. SMITH

(b) County of Residence of First Listed Plaintiff Washtenaw (MI)
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Kimberly Dougherty, Esquire - Janet, Jenner & Suggs, LLC
75 Arlington Street, Suite 500, Boston, MA 02116
T: (617) 933-1265; F: (410) 653-6903; E: kdougherty@myadvocates.com

DEFENDANTS
AMERIDOSE LLC, MEDICAL SALES MANAGEMENT INC., GDC PROPERTIES MANAGEMENT, LLC, BARRY J. CADDEN, LISA CONIGLIARO CADDEN, GLENN A. CHIN, et al.

County of Residence of First Listed Defendant Worcester County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	☒ 4
Citizen of Another State	☒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS
- ❒ 510 Motions to Vacate Sentence

Habeas Corpus:
- ❒ 530 General
- ❒ 535 Death Penalty
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Mgmt. Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from another district *(specify)* ❒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C.A. § 1332
Brief description of cause:
Defective Medical Product

VII. REQUESTED IN COMPLAINT:
❒ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23
DEMAND $ Over $75,000
CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ❒ No

VIII. RELATED CASE(S) IF ANY *(See instructions):*
JUDGE D.J. Saylor DOCKET NUMBER
MDL No. 1:13-md-2419-FDS

DATE 03/11/2013
SIGNATURE OF ATTORNEY OF RECORD /s/ Kimberly A. Dougherty

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

JS 44 Reverse (Rev. 09/11)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**. Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. **Title of case (name of first party on each side only)** WARREN L. SMITH, et al. v. AMERIDOSE LLC, et al.

2. **Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).**

☐	I.	**410, 441, 470, 535, 830*, 891, 893, 895, R.23, REGARDLESS OF NATURE OF SUIT.**
☐	II.	**110, 130, 140, 160, 190, 196, 230, 240, 290,320,362, 370, 371, 380, 430, 440, 442, 443, 445, 446, 448, 710, 720, 740, 790, 820*, 840*, 850, 870, 871.**
☑	III.	**120, 150, 151, 152, 153, 195, 210, 220, 245, 310, 315, 330, 340, 345, 350, 355, 360, 365, 367, 368, 375, 385, 400, 422, 423, 450, 460, 462, 463, 465, 480, 490, 510, 530, 540, 550, 555, 625, 690, 751, 791, 861-865, 890, 896, 899, 950.**

***Also complete AO 120 or AO 121. for patent, trademark or copyright cases.**

3. **Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.**

IN RE: New England Compounding Pharmacy, Inc. Products Liability Litigation - MDL No. 1:13-md-2419-FDS

4. **Has a prior action between the same parties and based on the same claim ever been filed in this court?**

YES ☐ **NO** ☑

5. **Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)**

YES ☐ **NO** ☑

If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?

YES ☐ **NO** ☐

6. **Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?**

YES ☐ **NO** ☑

7. **Do all of the parties in this action, excluding governmental agencies of the united states and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).**

YES ☐ **NO** ☑

A. If yes, in which division do all of the non-governmental parties reside?

Eastern Division ☐ **Central Division** ☐ **Western Division** ☐

B. If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?

Eastern Division ☑ **Central Division** ☐ **Western Division** ☐

8. **If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)**

YES ☐ **NO** ☑

(PLEASE TYPE OR PRINT)
ATTORNEY'S NAME Kimberly A. Dougherty
ADDRESS Janet, Jenner & Suggs, LLC - 75 Arlington St., Suite 500, Boston, MA 02116
TELEPHONE NO. (617) 933-1265

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

WARREN L. SMITH and KAREN SMITH *Plaintiff(s)* v. AMERIDOSE LLC, MEDICAL SALES MANAGEMENT INC., GDC PROPERTIES MANAGEMENT, LLC, BARRY J. CADDEN, LISA CONIGLIARO CADDEN, GLENN A. CHIN, GREGORY CONIGLIARO, and ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Ameridose, LLC
Registered Agent: Gregory Congiliaro
203 Flanders Rd.
Westborough, MA 01581

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly Dougherty, Esquire
Janet, Jenner & Suggs, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903
Email: kdougherty@myadvocates.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____ , a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

WARREN L. SMITH and KAREN SMITH *Plaintiff(s)* v. AMERIDOSE LLC, MEDICAL SALES MANAGEMENT INC., GDC PROPERTIES MANAGEMENT, LLC, BARRY J. CADDEN, LISA CONIGLIARO CADDEN, GLENN A. CHIN, GREGORY CONIGLIARO, and ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Ameridose, LLC
Registered Agent: Gregory Congiliaro
203 Flanders Rd.
Westborough, MA 01581

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly Dougherty, Esquire
Janet, Jenner & Suggs, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903
Email: kdougherty@myadvocates.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____ , a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

WARREN L. SMITH and KAREN SMITH *Plaintiff(s)* v. AMERIDOSE LLC, MEDICAL SALES MANAGEMENT INC., GDC PROPERTIES MANAGEMENT, LLC, BARRY J. CADDEN, LISA CONIGLIARO CADDEN, GLENN A. CHIN, GREGORY CONIGLIARO, and ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Ameridose, LLC
Registered Agent: Gregory Congiliaro
203 Flanders Rd.
Westborough, MA 01581

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly Dougherty, Esquire
Janet, Jenner & Suggs, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903
Email: kdougherty@myadvocates.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____ , a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

WARREN L. SMITH and KAREN SMITH *Plaintiff(s)* v. AMERIDOSE LLC, MEDICAL SALES MANAGEMENT INC., GDC PROPERTIES MANAGEMENT, LLC, BARRY J. CADDEN, LISA CONIGLIARO CADDEN, GLENN A. CHIN, GREGORY CONIGLIARO, and ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Ameridose, LLC
Registered Agent: Gregory Congiliaro
203 Flanders Rd.
Westborough, MA 01581

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly Dougherty, Esquire
Janet, Jenner & Suggs, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903
Email: kdougherty@myadvocates.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____ , a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

WARREN L. SMITH and KAREN SMITH *Plaintiff(s)* v. AMERIDOSE LLC, MEDICAL SALES MANAGEMENT INC., GDC PROPERTIES MANAGEMENT, LLC, BARRY J. CADDEN, LISA CONIGLIARO CADDEN, GLENN A. CHIN, GREGORY CONIGLIARO, and ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Ameridose, LLC
Registered Agent: Gregory Congiliaro
203 Flanders Rd.
Westborough, MA 01581

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly Dougherty, Esquire
Janet, Jenner & Suggs, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903
Email: kdougherty@myadvocates.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____ , a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

WARREN L. SMITH and KAREN SMITH *Plaintiff(s)* v. AMERIDOSE LLC, MEDICAL SALES MANAGEMENT INC., GDC PROPERTIES MANAGEMENT, LLC, BARRY J. CADDEN, LISA CONIGLIARO CADDEN, GLENN A. CHIN, GREGORY CONIGLIARO, and ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Ameridose, LLC
Registered Agent: Gregory Congiliaro
203 Flanders Rd.
Westborough, MA 01581

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly Dougherty, Esquire
Janet, Jenner & Suggs, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903
Email: kdougherty@myadvocates.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____ , a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

WARREN L. SMITH and KAREN SMITH *Plaintiff(s)* v. AMERIDOSE LLC, MEDICAL SALES MANAGEMENT INC., GDC PROPERTIES MANAGEMENT, LLC, BARRY J. CADDEN, LISA CONIGLIARO CADDEN, GLENN A. CHIN, GREGORY CONIGLIARO, and ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Ameridose, LLC
Registered Agent: Gregory Congiliaro
203 Flanders Rd.
Westborough, MA 01581

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly Dougherty, Esquire
Janet, Jenner & Suggs, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903
Email: kdougherty@myadvocates.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____ , a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

WARREN L. SMITH and KAREN SMITH *Plaintiff(s)* v. AMERIDOSE LLC, MEDICAL SALES MANAGEMENT INC., GDC PROPERTIES MANAGEMENT, LLC, BARRY J. CADDEN, LISA CONIGLIARO CADDEN, GLENN A. CHIN, GREGORY CONIGLIARO, and ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Ameridose, LLC
Registered Agent: Gregory Congiliaro
203 Flanders Rd.
Westborough, MA 01581

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly Dougherty, Esquire
Janet, Jenner & Suggs, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903
Email: kdougherty@myadvocates.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____ , a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: